

§ 13.15

Management on whether the nominees of the other persons meet the criteria established in paragraph (a) of this section. A person submitting comments to the Division of Dockets Management shall submit them to all persons entitled to submit a list of nominees.

(3) The lists of nominees and comments on them are to be held in confidence by the Division of Dockets Management as part of the administrative record of the proceeding and are not to be made available for public disclosure, and all persons who submit or receive them shall similarly hold them in confidence. This portion of the administrative record remains confidential but is available for judicial review in the event that it becomes relevant to any issue before a court.

(c) After reviewing the lists of nominees and any comments, the Commissioner will choose three qualified persons as members of a Board. One member will be from the lists of nominees submitted by the director of the center and by any person whose petition was granted and is the subject of the hearing. The second will be from the lists of nominees submitted by the other parties. The Commissioner may choose the third member from any source. That member is the Chairman of the Board.

(1) If the Commissioner is unable to find a qualified person with no conflict of interest from among a list of nominees or if additional information is needed, the Commissioner will request the submission of the required additional nominees or information.

(2) If a person fails to submit a list of nominees as required by paragraph (b) of this section, the Commissioner may choose a qualified member without further consultation with that person.

(3) The Commissioner will announce the members of a Board by filing a memorandum in the record of the proceeding and sending a copy to all participants.

(d) Instead of using the selection method in paragraphs (b) and (c) of this section, the director of the center, the other parties to the proceeding, and any person whose petition was granted and is the subject of the hearing, may, with the approval of the Commissioner, agree that a standing advisory committee listed in §14.80 constitutes the

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Board for a particular proceeding, or that another procedure is to be used for selection of the members of the Board, or that the Board consists of a larger number of members.

(e) The members of a Board serve as consultants to the Commissioner and are special Government employees or Government employees. A Board functions as an administrative law tribunal in the proceeding and is not an advisory committee subject to the requirements of the Federal Advisory Committee Act or part 14.

(f) The Chairman of the Board has the authority of a presiding officer set out in §12.70.

[44 FR 22348, Apr. 13, 1979, as amended at 50 FR 8994, Mar. 6, 1985]

§ 13.15 Separation of functions; ex parte communications; administrative support.

(a) The proceeding of a Board are subject to the provisions of §10.55 relating to separation of functions and ex parte communications. Representatives of the participants in any proceeding before a Board, including any members of the office of the Chief Counsel of FDA assigned to advise the center responsible for the matter, may have no contact with the members of the Board, except as participants in the proceeding, and may not participate in the deliberations of the Board.

(b) Administrative support for a Board is to be provided only by the office of the Commissioner and the office of the Chief Counsel for FDA.

[44 FR 22348, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989]

Subpart B—Hearing Procedures

§ 13.20 Submissions to a Board.

(a) Submissions are to be filed with the Division of Dockets Management under §10.20.

(b) The person making a submission shall serve copies of it on each participant in the proceeding, except as provided in §§13.10(b)(2) and 13.45. Submissions of documentary data and information need not be sent to each participant, but any accompanying transmittal letter, summary, statement of position, certification under paragraph